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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,307	01/11/2001	Sam J. Milstein	1946/1A483-US8	8759

7590

12/03/2001

DARBY & DARBY P.C.  
805 Third Avenue  
New York, NY 10022

EXAMINER
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CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/03/2001

7

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/760,307

Applicant(s)

MILSTEIN ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-127 is/are pending in the application.
- 4a) Of the above claim(s) 54, 56-59, 63, 65-68, 75-119 and 4049 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 50-53, 55, 60-62, 64, 69-74 and 120-127 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☒ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 6. 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Receipt of IDS, dated 8-6-01; request for extension of time, amendment A and response, all dated 9-28-01; and supplemental IDS, dated 10-9-01 is acknowledged.

#### ***Election/Restrictions***

Applicant's election with traverse of Group II(B)(2) in Paper No. 5 is acknowledged.

The traversal is on the ground(s) that the compositions of group II are administered by the method recited in the claims of Group I. This is not found persuasive because the claims directed to method of delivery recite several routes of administration. Accordingly, the composition of group I could be administered or delivered by several routes, which are different from each other.

The requirement is still deemed proper and is therefore made FINAL.

Claims 50-53, 55, 60-62, 64, 69-74 and 120-127 read on the elected species and are considered for prosecution. Claims 1-49, 54, 56-68, 63, 65-68 and 75-119 are withdrawn from consideration.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 50-53, 55, 60-62, 64, 69-74 and 120-127 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 and 24-29 of U.S. Patent No. 5,935,601. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic for the acylated amino acid or acylated peptide carriers, which encompass the species claimed in the patent. The patented "composition" is generic and includes the compositions deliverable any of the known methods in the art. Absent showing evidence on the contrary, the patented compositions are deliverable sublingually, as required by the instant claims. Accordingly, it would have been obvious for a skilled artisan to use the composition of the patent for sublingual delivery of biologically active agents because the patent teaches the same carriers that are within the scope of the instant claims.

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Claims 50-53, 55, 60-62, 64, 69-74 and 120-127 are directed to an invention not patentably distinct from claims 1-22 and 24-29 of commonly assigned 5,935,601. Specifically, the instant claims are generic for the acylated amino acid or acylated peptide carriers, which encompass the species claimed in the patent.

Commonly assigned patent, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 50-53, 55, 60-62, 64, 69-74 and 120-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over UD50-53, 55, 60-62, 64, 69-74 and 120-127 US 5,935,601 ('601).

'601 teach compositions containing a biologically active agent and modified amino acids as carriers for drug delivery (entire document). In particular, the carriers are the same as claimed in the instant i.e., acylated amino acids or peptide (which is nothing but a polyamino acid) (col. 4, lines 1 through col. 5, lines 62). '601 also teach using modified amino acids directly as a drug delivery carrier or in the form of microspheres (col. 8). Accordingly, it is not necessary that the microspheres are formed and thus meets the claim limitation "biological agent not forming a microsphere with the perturbant". '601 teach the biological active agents suitable for delivery with the above carriers in col.3, lines 10-56. While '601 teach oral intraduodenal and other routes of administering the active agent and carrier, '601 fails to specifically mention "sublingual" route. However, absent showing evidence on the contrary, the composition of '601 is sublingually deliverable because the composition claims and taught by '601 are similar. Further, the instant claims recite the delivery route as an intended use and it is well established that the intended use in a claim carries no patentable distinction. Therefore, it would have been within the scope of a skilled artisan to deliver the composition of '601 in a sublingual route and still expect successful delivery of the biological agent.

Claims 50-53, 55, 60-62, 64, 69-74 and 120-127 are rejected under 35 U.S.C. 103(a) as being obvious over US 5,935,601.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This

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rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

'601 teach compositions containing a biologically active agent and modified amino acids as carriers for drug delivery (entire document). In particular, the carriers are the same as claimed in the instant i.e., acylated amino acids or peptide (which is nothing but a polyamino acid) (col. 4, lines 1 through col. 5, lines 62). '601 also teach using modified amino acids directly as a drug delivery carrier or in the form of microspheres (col. 8). Accordingly, it is not necessary that the microspheres are formed and thus meets the claim limitation "biological agent not forming a microsphere with the perturbant". "601 teach the biological active agents suitable for delivery with the above carriers in col.3, lines 10-56. While '601 teach oral intraduodenal and other routes of administering the active agent and carrier, '601 fails to specifically mention "sublingual" route. However, absent showing evidence on the contrary, the composition of '601 is

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sublingually deliverable because the composition claims and taught by '601 are similar. Further, the instant claims recite the delivery route as an intended use and it is well established that the intended use in a claim carries no patentable distinction. Therefore, it would have been within the scope of a skilled artisan to deliver the composition of '601 in a sublingual route and still expect successful delivery of the biological agent.

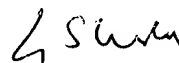
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7921 for regular communications and 703-308-7921 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi S. Channavajjala  
Examiner  
Art Unit 1615  
November 29, 2001



Gollamudi S. Kishore, PhD  
Primary Examiner  
Group 1600

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